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MEDICAL BREATHING CIRCUIT SCAVENGER SYSTEM
USER'S MANUAL / INSTRUCTIONS

Examination

All components should be removed from their respective shipping containers and examined. Any omissions and/or damage should be reported to your Porter dealer immediately.

User Responsibility

The Medical Breathing Circuit Scavenger System (with Porter disposable Medical Breathing Circuit) is designed for use with Nitronox® HD Inhalation Analgesia System (Refer to Instructions FM-1308), or an Analgesia Conscious Sedation Flowmeter (Refer to Analgesia Conscious Sedation Device Instructions) to perform in accordance with specifications herein when installed, operated and maintained as instructed in this manual. It should be carefully read and understood prior to operation and use of the scavenger system.

Warnings (administration of N_2O/O_2 conscious sedation analgesia)

- The Scavenger System is intended to be used by medical personnel trained in its use and the use of nitrous oxide and oxygen for medical applications.
- An EXPLOSION hazard exists when flammable agents are exhausted into the vacuum system (Page 5).
- The Scavenger Interface is supplied with a removable foam flow resistor. This foam resistor must be REPLACED every six months to help prevent the possibility of increased resistance due to particle entrapment (Page 8).
- **Use Scavenging:** Medical workers are exposed to N_2O during administration of N_2O/O_2 conscious sedation analgesia. Controls are effective in the patient treatment area to achieve low levels of ppm (parts per million) exposure. Controls include System Maintenance, Ventilation and Work Practices. Your accessory Scavenger System is an important part of the system of controls in medical settings.

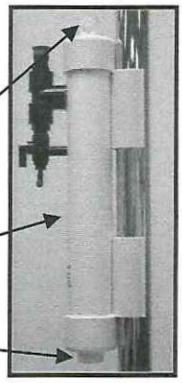
Warning: When using a single use full face mask or mouthpiece dispose of mask after use to prevent patient cross-contamination. When using sterilizable mask, follow manufacturer's sterilization instructions.

Warning: Use patient observation to prevent over sedation. If a patient becomes over sedated when being delivered 100% oxygen [during an apparent loss of nitrous oxide supply], it is a definite indication of crossed lines. If crossed lines are suspected, remove the mask immediately and encourage mouth breathing. Deliver pure oxygen only if the oxygen source is independent from the suspected crossed lines area.

Medical Breathing Circuit Scavenger System - Description

The Medical Breathing Circuit Scavenger System is an Interface for the removal of patient exhaled O_2 / N_2O gas mixtures generated from the Nitronox Inhalation Analgesia System or the Conscious Sedation Flowmeter System and Medical Breathing Circuit. The exhaled gases are routed through the Interface to a vacuum system. The Scavenger and vacuum systems provide dilution and disposal of mixed waste gases. The Scavenger System consists of components necessary to transfer patient exhaled gas mixtures to the source of vacuum.

Fig. 1.1
Interface



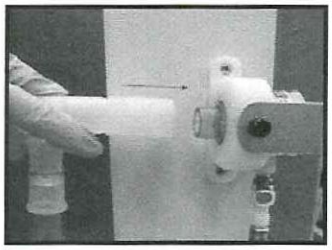


Fig. 1.2 Nitronox

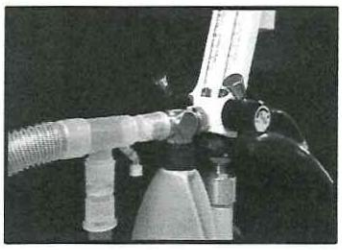


Fig. 1.3 Porter MXR

Fig. 1.4
19mm Hose

Fig. 1.5 Sentry Sedate

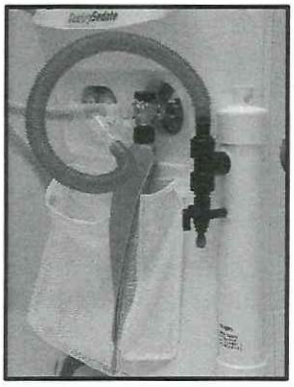


Fig. 1.6 Gas Output
Sentry Sedate

The system components are:

- A Scavenger Interface (Fig. 1.1) to connect the vacuum system with the Scavenger System. It contains:
  - Orifices to limit vacuum pressure and flow.
  - Opening to ambient to help prevent over/under pressurization from patient exhaust.
  - A valve to automatically drain any internal condensation.

- A Nitronox Demand Valve Mount (Fig. 1.2) to seal the exhaust ports of the Demand [breathing] Valve, or

- A Flowmeter with Bag Tee (Fig. 1.3) to deliver the Conscious Sedation mixture to the Medical Breathing Circuit (using Breathing Circuit "tee.").

- A corrugated magenta 19mm hose (Fig. 1.4) with one way valve to connect the Medical Breathing Circuit to the Interface. The hose is an integral part of the disposable Medical Breathing Circuit.

- The Interface is typically connected to the center post on a Mobile Cart or Wall (see FM-916 for E-Stand and FM-1346 for 2-Cylinder Mobile Cart). For Sentry Sedate see FM-1274 (see Fig. 1.5, Fig. 1.6; Note: A Porter Bag Tee attaches to the Gas Output Bulkhead prior to attachment of the Medical Breathing Circuit.).

Medical Breathing Circuit Scavenger System - Description

The gas flow path through the Scavenger System starts with patient exhalation from the mask into the coaxial tubing of the disposable Medical Breathing Circuit and then to the tee of the Medical Breathing Circuit through the one-way valve into the 19 mm scavenger hose. The flow path is one-way directional and reinforced with a one-way valve. The hose leads the gas into the Scavenger Interface. The Interface is open at the top to ambient via a foam resistor. In addition, the Interface contains an internal pathway for gas passage permitting waste gas to follow a preferential path to vacuum.

From the internal pathway of the Interface, the waste gas flows through a ball-type control valve to a calibrated orifice contained within the barbed vacuum connector. The final gas path is through the vacuum hose to the vacuum outlet.

If vacuum flow through the calibrated orifice exceeds the exhaled flow from the patient, room air will be drawn from ambient into the vacuum system via the Scavenger Interface. Also the internal volume of the Interface acts as a surge chamber to absorb a short duration of excessive patient exhalation flow. During this short duration, excess gas will fill the Interface allowing time for the vacuum flow to exhaust the gas during the next patient inspiration. Control of scavenging vacuum flow to the vacuum source through the orifice is provided by the ball control valve. The ball valve adjusts the scavenging vacuum flow between an upper (maximum) and a lower (minimum) limit. Higher vacuum flows assist in scavenging higher levels of patient exhalation flow.

An automatic relief valve is provided in the bottom of the Interface to prevent condensation from causing a water seal of any internal gas passages. This is feature operates only when condensation occurs.

Installation Options

Mobile Stand Mount

Connect the cylindrical Scavenger Interface to the center column assembly of the Mobile Stand (Figs. 2.1, 2.2). Use the mounting clips of the Interface to position the assembly on the column. Orient the Interface assembly vertically with open end (foam resistor) up and condensation relief drain valve down.

Fig. 2.1

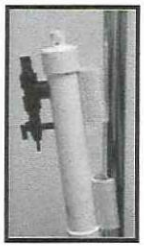
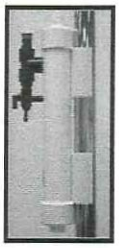


Fig. 2.2



Wall Mount: Fig. 3

1. Hold the Scavenger Interface against the wall in the desired mounting location. The 19 mm magenta corrugated hose is 2 ft. long (61 cm) and must connect to the Analgesia Conscious Sedation Device output and the Scavenger Interface.

2. Mark four mounting-hole locations on wall using the Interface mounting plates as templates.

3. Drill four holes in the locations marked:

   Note:
   - For dry wall or plaster, use a suitable screw attachment method to secure against pushing and pulling of hose connections.
   - For wooden studs, drill appropriate pilot hole, 1-1/2 inches (4 cm) deep to accept mounting screws.

4. Insert appropriate receptacle (not provided) in hole, if necessary.

5. Mount the Scavenger Interface using four screws (not provided) in the prepared locations (Fig. 3). **Note:** Mounting installation must be done on both the top and the bottom brackets.

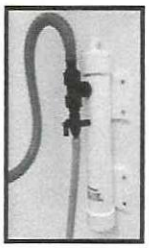
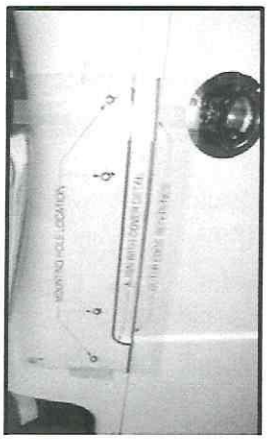


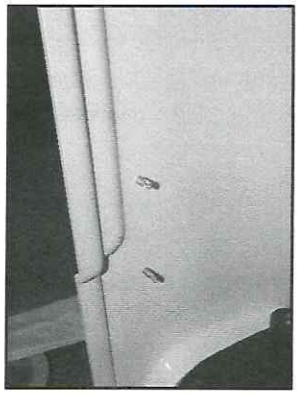
Fig. 3 Scavenger Wall Mount

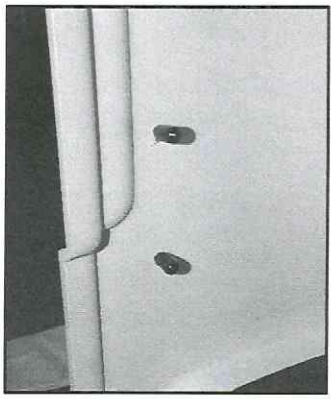
Scavenger Interface Mounted on Sentry Sedate



Use of template / kit
Fig. 3.1

On front cover
Fig. 3.2





Screws inside cover (place caps)
Fig. 3.3

1. If holes are not pre-drilled, use LB-730 Plastic Template to align with Front Cover and mark hole locations and drill appropriate pilot holes or use the self-tapping feature of the included mounting screws (See Fig. 3.1).

2. The Scavenger Interface mounts on the Front Cover of the Sentry Sedate using 4 screws through mounting plates and 4 holes in Front Cover (See Fig. 3.2)

3. Protective caps for the screw ends inside the cover are provided (See Fig. 3.3

Hose Connections: Fig. 4

1. Connect the 19 mm magenta corrugated scavenger hose of the disposable Medical Breathing Circuit to the Interface (Fig. 4.1).

2. Connect vacuum hose between the vacuum source inlet (using appropriate connection such as DISS, QUICK Connect, etc.) and the barbed outlet connector on the Interface. Push the tubing on the barb so that two to three barbs are covered.

Note: Hold the barbed outlet while pushing tubing onto barb to reduce excess strain.

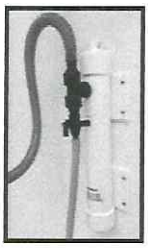


Fig. 4.1

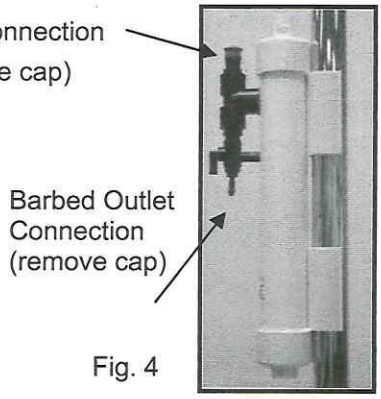


Fig. 4

Warning

An explosion hazard exists when flammable agents are exhausted into the central vacuum system.1

Operation

Fig. 5

1. Connect Wall, Mobile E-Stand, or Sentry Sedate gas supplies [O_2 and N_2O] to Nitronox or Flowmeter. Connect vacuum source to Scavenger Interface barb.
2. Ensure Interface black lever valve is in the on [open] position before beginning procedure. For best scavenging vacuum flow, turn the ball valve lever to the vertical (full on position; 6 o'clock) (Fig. 5).

   Note: With the ball valve lever in the full on position, the vacuum flow should accommodate the exhaust gas from all normal breathing patterns (30 – 35 LPM, maximum).
3. If the overall demand for vacuum is overloading the central system, the ball valve may be slightly throttled to reduce vacuum flow by turning the ball lever to the 7 to 8 o'clock position.

   Note: With the lever in the mid 7 to 8 o'clock position, the ball valve will still allow a vacuum flow of 8 to 12 LPM, minimum. Minimal flow position is 9 o'clock.
4. **Removal of ball valve lever to "lock-in" adjustment position:** Remove holding screw and ball valve lever after adjustment to full on position [eliminates inadvertent lever position change]. To place lever back again for adjustment capability, take care to slide into full on, 6 o'clock position and assure lever range is from 6 o'clock to 9 o'clock.
5. The Interface is designed so that condensed water vapor should discharge from the bottom, if its volume exceeds 40 to 50 cc/mL.
6. Read and follow the directions in the Instructions FM-1329: Using the Porter Medical Breathing Circuit with Nitronox (Demand Flow) or with Analgesia Conscious Sedation (Continuous Flow) Devices.

Maintenance

Cleaning

We recommend the use of an approved disinfectant or surface wipe for the dental / medical environment for cleaning the **outside** of the Scavenger System. Do not spray disinfectant directly onto housing. Spray disinfectant into disposable towel and wipe unit thoroughly removing excess disinfectant to eliminate buildup.

CAUTION: Introduction of moisture or other contaminants into this device may result in defective operation.

CAUTION: Never oil or grease any part of this system (minimize fire or explosion potential).

Field Replacement Foam Resistor

1. Replacement of the foam flow resistor PN 61962300 (refer to Figure 1.1) approximately every six months.

   Warning

   The foam flow resistor is to be replaced approximately every 6 months to help prevent the possibility of increased resistance due to particle entrapment.
2. Pull the foam resistor (one inch, diameter, by six inches, long) from the top center hole of the Interface cylinder with the use of forceps or needle nose pliers.
3. Insert a new foam resistor into the Interface top-center hole until the top of the foam resistor reaches the lower edge of the horizontal vent holes.

Replacement Parts: Contact Porter or your authorized Porter Dealer

Development of Delivery Protocols

It is the responsibility of the medical establishment and the medical professional to develop and establish specific delivery protocols.

The Nitronox Inhalation Analgesia System is designed to deliver a fixed concentration of 50% nitrous oxide and 50% oxygen on the demand flow [self-administration] principle. The Conscious Sedation Flowmeter with Bag Tee is designed to deliver a variable concentration of nitrous oxide and oxygen on the continuous flow principle. The medical professional will turn on and observe the operating indicators of the device. In order to receive the analgesic, the patient may assist [Nitronox: will self-administer] by holding the face mask firmly in place during the procedure. With the face mask sealed every time the patient takes a breath, the patient will receive the full effect of the mixed gas through the face mask [Nitronox: the patient inhalation will open the demand valve].

Common procedures conducted with Nitrous Oxide – Oxygen Analgesia Conscious Sedation.

Ideal for minimally invasive procedures where there is a desire for pain management to reduce anxiety or to deliver minimal sedation.

The Nitronox Inhalation Analgesia System and the Conscious Sedation Flowmeter delivery is considered transient (less than 60 minutes) in terms of continuous use when providing Analgesia (pain management), or Minimal Sedation. However, a procedure or medical condition that occurs over the course of many hours, also is considered to be using transient delivery, in that, given administration techniques, the patient will be unlikely to hold the face mask to the face continuously for over 60 minutes. For example, a woman in labor may safely use conscious sedation (typically using a Porter Demand Flow Nitronox device) in a transient self-administration mode over the course of several hours as secondary labor and end labor stages are experienced. The upper limit of the number of hours of this described transient delivery is at the determination of the medical professional.

> Patient Population (Adult and Pediatric): Used to deliver a gas mixture to a conscious spontaneously breathing patient who is awake, alert and cooperative and requires relief from minimal to moderate pain and is under the continuous supervision of a healthcare professional. Age/Weight limitations: see Relative Contraindications (at the determination of medical professional).

Note: Porter recommends the use of a disposable full face mask (DEHP-free and Latex-free) that is biocompatible for medical use. Follow manufacturer's instructions. The disposable mask materials have been chosen by the medical device manufacturers of the masks intended for medical usage. Many establishment protocols also call for the use of a bacterial filter. Follow manufacturer's instructions.